July 23, 2026

Velmeni, Inc.
% Mini Suri
CEO
333 W. Maude Ave.
SUNNYVALE, CA 94085

Re: K254096
Trade/Device Name: VELMENI for DENTISTS (V4D) 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 18, 2026
Received: June 22, 2026

Dear Mini Suri:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254096

Device Name
VELMENI for DENTISTS (V4D) 3D

Indications for Use *(Describe)*

VELMENI for DENTISTS (V4D) 3D is radiological, automated, concurrent read, computer-assisted detection software intended to assist in the clinical detection of anatomical structures (maxilla plus cranium, mandible, mandibular canal, temporomandibular joint, maxillary sinus ,teeth ,airway) in CBCT radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for licensed dental professionals in examining radiographs of patients' teeth. The device is not intended as a substitute for a complete examination by the dental professional or their clinical judgment that considers other relevant information from the patient's history or actual in-vivo clinical assessment. Final diagnoses and patient treatment plan are the responsibility of the dental professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VELMENI for DENTISTS (V4D) 3D

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for VELMENI for DENTISTS (V4D) 3D is provided:

Submitter Information

Submitter:	Velmeni Inc. 333 West Maude Avenue, STE 207 Sunnyvale, CA 94085 Phone: 201-289-3500
Date Prepared:	July 22, 2026
Contact Person:	Mini Suri, CEO Velmeni Inc. Phone: 201-289-3500 Email: mini@velmeni.com

Identification of the Device

Trade Name:	VELMENI for DENTISTS (V4D) 3D
Common Name:	Medical image management and processing system
Classification Name	Medical image management and processing system 21 CFR 892.2050
Product Code:	QIH
Device Class:	Class II

Predicate Device

Predicate Device: Pearl Second Opinion 3D (K243989)

Device Description

V4D 3D introduces 3D image processing to the VELMENI AI platform. The device comprises of the following key components

- Web Application Interface delivers front-end capabilities and is the point of interaction between the device and the user.
- Machine Learning (ML) Engine delivers V4D's core ML capabilities for 2D and 3D imaging.
- Backend API allows interaction between all the components, as defined in this section, in order to fulfill the user & requests on the web application interface.
- Queue receives and stores messages from Backend API to send to AI-Worker.
- AI-Worker accepts 3D scan analysis requests from Backend API via the Queue.
    - For 3D, DICOM scans (in .zip format) are passed via Backend API in nifti format to the appropriate 3D ML engine.The ML analysis results are returned to the Backend API.
- Database and File Storage store critical information related to the application, including user data, patient profiles, analysis results,3D scans and associated data.

The following non-medical interfaces are also available with VELMENI for DENTISTS (V4D) 3D

- VELMENI BRIDGE (VB) acts as a conduit enabling data and information exchange between Backend API and third-party software like Patient Management or Imaging Software

Intended Use/ Indications for Use

VELMENI for DENTISTS (V4D) 3D is radiological, automated, concurrent read, computer-assisted detection software intended to assist in the clinical detection of anatomical structures (maxilla plus cranium, mandible, mandibular canal, temporomandibular joint, maxillary sinus ,teeth ,airway) in CBCT radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for licensed dental professionals in examining radiographs of patients' teeth. The device is not intended as a substitute for a complete examination by the dental professional or their clinical judgment that considers other relevant information from the patient's history or actual in-vivo clinical assessment. Final diagnoses and patient treatment plan are the responsibility of the dental professional.

Technological Comparison

The proposed **VELMENI for DENTISTS (V4D) 3D** device is substantially equivalent to the primary predicate device; Pearl Second Opinion 3D K243989

Specification	**Proposed Device**	**Predicate Device**
Manufacturer	Velmeni Inc.	Pearl
Classification	892.2050	892.2050
Product Code	QIH	QIH
Image Modality	CBCT Radiograph	Radiograph
Intended Body Part	Dental Structures	Dental Structures
End User	Licensed dental professional	Dentist
Patient Population	Patients requiring dental services, all sexes, at least 15 years of age, and with permanent dentition.	Patients 12 years of age or older
Prescription or OTC	Prescription Use	Prescription Use

Reader Workflow	Concurrent Read	Concurrent Read
Image Source	DICOM	Unknown
Cloud Hosted Software	Yes	Yes
Platform	Web – Safari, Edge, Chrome, Firefox	Web
User Interface	Mouse, keyboard, trackpad	Mouse, keyboard, trackpad
Data Input	CBCT Images	CBCT Images
Data Output	AI Detection of non-pathological (maxilla, mandible, mandibular canal, temporomandibular joint, maxillary sinus, teeth, airway), Panoramic viewer for automated dental arch and SLT file export “For educational and research purposes only; not intended for 3D printing or treatment planning”	Dentition, Maxilla, Mandible, Inferior Alveolar Canal and Mental Foramen (IAN), Maxillary Sinus, Nasal space, and airway
Segmentation	Segmentation on radiograph	Segmentation on radiograph
Tooth Number Module	Yes	No
Model (Algorithm Type)	Machine Learning	Computer vision and Machine Learning

Performance Data

Software Verification and Validation Tests:

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submission for Device Software Functions." Verification of the software was conducted to ensure that the product works as designed. Validation was conducted to validate the design and the performance of the device to meet user needs and intended uses. VELMENI for DENTISTS (V4D) 3D passed all verification and validation software tests.

Bench Testing:

The standalone analysis evaluating segmentation and correct labeling demonstrated the Velmeni 3D CBCT algorithm performance. 127 de-identified digital images were collected from 4 separate US dental offices representative of the general population. The data collected had representation from 3 manufacturers(INSTRUMENTARIUM DENTAL, Planmeca and Sirona) with 20 or more cases, constituting 87% of the test cases. A subgroup analysis was performed that included the following categories: scanner type, sex, and age categories (≤40, 41-64, >64 and 15-21, 22-49, and >= 50).

Based upon the bench testing performed it was determined that the proposed device performed similarly to the predicate

Table 1 Mean DICE and Sensitivity for V4D Software - Airway, Canal, Mandible, Maxilla, Sinus and TMJ

Assessment	DICE Mean	Sensitivity(95% CI)
Airway	0.968 (95% CI: 0.96, 0.974)	99.2%(97.6%, 100.0%)
Mandibular canal (Canal)	0.914 (95% CI: 0.903, 0.924)	96.8%(93.5%, 99.2%)
Mandible	0.952 (95% CI: 0.949, 0.956)	100.0%(97.1%, 100.0%)
Maxilla plus cranium (Maxilla)	0.951 (95% CI: 0.947, 0.955)	100.0%(97.1%, 100.0%)
Maxillary Sinus (Sinus)	0.96 (95% CI: 0.9, 0.9)	100.0%(97.1%, 100.0%)
Temporomandibular joint (TMJ)	0.950 (95% CI: 0.937, 0.961)	96.9%(94.2%, 99.1%)

Table 2 Mean DICE,Sensitivity & Specificity for V4D Software - Teeth

Assessment	DICE Mean	Sensitivity(95% CI)	Specificity(95% CI)
Teeth	0.957 (95% CI: 0.952, 0.962)	96.9%(95.8%, 98.0%)	99.4%(98.7%, 99.9%)
Teeth (imputing 0 for missed teeth*)	0.944 (95% CI: 0.935, 0.953)	-	-

*This includes a small number of teeth (1.3% of all teeth) not identified by the algorithm but indicated by the ground truth which were imputed as 0 for the DICE analysis .

Table 3 Tooth Labeling Accuracy for V4D Software

Assessment	Accuracy(95% CI)
Overall Correct Tooth Labeling	98.6%(97.9%, 99.1%)
Images with 100% Overall Correct Tooth labeling	77.0%(69.0%, 84.1%)

Conclusion

Both the predicate device and the proposed VELMENI for DENTISTS (V4D) 3D device share the same intended purpose. Despite minor technological differences, these differences in technological features do not raise concerns regarding safety or effectiveness. Following the information reviewed as part of this 510k, it can be concluded that the VELMENI for DENTISTS (V4D) 3D is substantially equivalent to the predicate device.